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BOOK 1 OF 2 BOOKS

FRIDAY, MARCH 17, 1978

highlights

CHICAGO, ILLINOIS WORKSHOPS

HOW TO USE THE FEDERAL REGISTER

FOR: Any person who must use the Federal Register and Code of Federal Regulations.

WHAT: Free public workshop (approximately 3 hours) to present:

1. Brief history of the Federal Register system.
2. Difference between legislation and regulations.
3. Relationship of Federal Register and the Code of Federal Regulations.
4. Important elements of a typical Federal Register document.
5. An introduction to the finding aids of the FR/CFR system.

WHEN: April 12, 13, and 14, 1978 at 9 a.m. (Each session identical)

WHERE: Everett M. Dirksen Federal Building, Conference Room 572, 219 S. Dearborn Street, Chicago, Illinois.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them, as part of the General Services Administration's efforts to encourage public participation in government actions. There will be no discussion of specific agency regulations.

RESERVATIONS: Call Ardean Merrifield, Area Code 312-353-4242 or 353-0339.

CONTINUED INSIDE

SUBCHAPTER H—MEDICAL DEVICES

PART 801—LABELING

Subpart H—Special Requirements for Specific Devices

7. By adding new § 801.417 to read as follows:

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

Effective dates. These regulations shall be effective on December 15, 1978, for the manufacturing or packaging of products subject to this regulation, and April 15, 1979, for the initial introduction into interstate commerce of products subject to this regulation.

(Secs. 301, 402, 409, 501, 502, 505, 507, 512, 601, 701(a), 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1049-1054 as amended, 1055, 57 Stat. 463 as amended, 72 Stat. 1785-1788 as amended, 82 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b, 361, 371(a)); sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332).)

Dated: February 3, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-6039 Filed 3-9-78; 8:45 am]

[6560-01]

Title 40—Protection of Environment

[FRL-865-6]

CHAPTER 1—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER R—TOXIC SUBSTANCES CONTROL ACT

PARTS 712, 762—FULLY HALOGENATED CHLOROFLUOROALKANES

AGENCY: Environmental Protection Agency.

ACTION: Final rules.

SUMMARY: On May 13, 1977, the Environmental Protection Agency (EPA) proposed a rule (42 FR 24542) which would prohibit almost all of the manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes (hereinafter referred to as chlorofluorocarbons) for those aerosol propellant uses which are subject to the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq. This rule and a related rule on reporting are now being promulgated in final form and will become effective October 15, 1978.

In a related action, the Food and Drug Administration (FDA) is publishing a final rule in today's FEDERAL REGISTER to ban the use of chlorofluorocarbon aerosol propellants in most food, drug, and cosmetic products.

The intent of these rules is to reduce emissions of chlorofluorocarbons to the atmosphere, thereby reducing the health and environmental risk caused by depletion of the ozone layer.

The promulgation of these rules concludes the first phase of EPA's investigation of chlorofluorocarbon emissions. A second phase investigation involving the nonaerosol propellant uses (e.g., refrigeration, foam blowing, and solvent) is ongoing.

EFFECTIVE DATES: October 15, 1978: Prohibition of Manufacturing. December 15, 1978: Prohibition of Processing and Distribution in Commerce.

INFORMATION CONTACT:

Perry Brunner, Office of Toxic Substances (TS-788), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-426-9000.

Joni T. Repasch is the Record and Hearing Clerk for this rulemaking. The official record of rulemaking is located in Room 520 WSME, EPA Headquarters, 401 M Street SW., Washington, D.C. 20460, 202-755-1188. The record is available for viewing and copying from 9 a.m. to 4 p.m., Monday through Friday, excluding holidays.

SUPPLEMENTARY INFORMATION: Under TSCA § 6 and its implementing regulations, 42 CFR 750, EPA is required to publish a statement discussing the factual, legal, analytical, and policy considerations which led to issuance of the rule, including the factors listed in TSCA § 6(c)(1). This preamble, the preamble to the proposed rule, the "Final Support Document," and the "Essential Use Determinations—Revised" are intended to fulfill that requirement.

Other major documents in the record are "Chlorofluorocarbon Problem Assessment" and "Economic Impact of Potential Regulation of Fluorocarbon Aerosols".

A list of all material in the record is found at the end of this preamble. Copies of the major documents may be obtained from Mrs. Joni Repasch at the address stated above.

I. EFFECTS OF CHLOROFLUOROCARBONS ON HEALTH AND THE ENVIRONMENT

Chlorofluorocarbons produce a risk to human health and the environment by causing depletion of the ozone layer. Upon release from an aerosol product or other source, the compounds diffuse slowly to the stratosphere. When they reach the stratosphere, they undergo photochemical decomposition which liberates free chlorine radicals. The chlorine radicals enter into a catalytic chain reaction with ozone molecules, and the net result is a depletion of the ozone layer.

The ozone layer helps shield the Earth's surface from ultraviolet (UV) radiation. As the layer is depleted, the Earth's surface is bombarded with more UV radiation. Current estimates are that if chlorofluorocarbon emissions continue at the 1975 rate, the ozone layer would be depleted ultimately by 11 to 16 percent.

While the effects of ozone depletion are very difficult to quantify, they are quite serious. The major immediate concern is that increased UV radiation leads to a statistically significant increase in skin cancer. Some negative effects on plants and animals are likely. There are also predictions of adverse effects because of an increase in the Earth's temperature ("greenhouse effect") and changes in climate. The health and environmental consequences of these and other changes are not well understood. However, there is considerable concern that these consequences will produce significant adverse effects.

II. USES, BENEFITS, AND ALTERNATIVES

In 1975, approximately one-half of the chlorofluorocarbons produced in the United States were used as aerosol propellants. Since then this figure has dropped considerably. Of the nonaerosol production, approximately one-half is used as refrigerants, and most of the remainder is used as solvents and foam blowing agents.

Chlorofluorocarbons are frequently the preferred propellant in aerosol products because of their nonflammability, their excellent dissolving (solvent) ability, and their fine spray characteristics. However, hydrocarbon and carbon dioxide propellants are available as alternatives to chlorofluorocarbons for many aerosol products. In addition, there are nonaerosol

alternatives such as pump sprays, waxes, liquids, and powders for most aerosol uses. In those cases where there is no alternative to a chlorofluorocarbon spray and the use appears essential, the Administrator has provided for exemptions from this regulation.

III. Economic Considerations

Over the past few years, use of chlorofluorocarbon aerosol propellants has decreased substantially. Five years ago, chlorofluorocarbons were used in 50 percent of aerosol products; it is estimated that they are now used in 20 percent. Because of the reduction in use, the economic impact of implementing EPA's rules will be much smaller than it would have been had they become effective sooner. The economic effects will be felt by three major groups in the chlorofluorocarbon industry: manufacturers, processors (fillers), and distributors (marketers). The combined impact of the EPA and FDA rules is expected to affect significantly the manufacturers and the fillers. EPA believes that the distributors are capable of switching to other products without significant costs.

Decreased sales of chlorofluorocarbon propellants have a direct impact both on the manufacturers of chlorofluorocarbons and the manufacturers of their chemical precursors. However, most of these manufacturers are large corporations which should be able to make the financial adjustment.

Fillers, on the other hand, will be significantly affected, and some probably will be severely affected. However, singling out small fillers for special treatment would undercut the effect of this regulation, lead to other economic dislocations, and hamper the Agency's enforcement efforts.

Consumers of household products stand to gain financially. Products containing chlorofluorocarbon propellants are more expensive per application than are products containing alternative propellants and nonaerosol products. Industrial consumers may have to make adjustments in products or processes. However, the essential use exemptions should alleviate any major adverse impact on industrial production outside the chlorofluorocarbon industry. Adverse effects on technological innovation are not expected.

IV. Finding of Unreasonable Risk

The Administrator finds that the continued depletion of stratospheric ozone as the result of discharges from nonessential aerosol products containing fully halogenated chlorofluoroalkane propellants presents an unreasonable risk of injury to health and the environment. Since this finding was proposed (42 FR 24545, May 13, 1977), the Administrator has reviewed the numerous comments received and the new scientific data which has become available. The Administrator remains convinced that promulgation of this rule at this time is necessary in order to reduce the risk of injury from chlorofluorocarbon aerosol propellant emissions to an acceptable level. A full explanation of his reasons and response to comments appears in the "Final Support Document."

Because chlorofluorocarbon emissions anywhere in the world deplete the ozone layer and adversely affect health and the environment of the United States, the Administrator finds that chlorofluorocarbon discharges from aerosol propellant articles made in the United States and shipped abroad also cause an unreasonable risk of injury.

V. Least Burdensome Approach

EPA has taken steps to reduce the burden of this regulation. Foremost was the decision to postpone a finding of unreasonable risk associated with nonpropellant uses until they are investigated more fully. Secondly, exemptions have been given for certain essential uses including nonconsumer electronics/electrical and aviation uses. In addition, by making the manufacturing ban effective 18 months from the proposal date instead of making it effective sooner, the Administrator has significantly reduced the economic impact.

EPA rejects the idea of requiring warning labels on chlorofluorocarbon products as an alternative to this rule. EPA believes that a labeling requirement would be insufficient to reduce the unreasonable risk from chlorofluorocarbon aerosol emissions. In addition, the Agency believes that the continued use of chlorofluorocarbons by some consumers will result in the involuntary exposure of the entire public to hazards created by the user population.

VI. Relationship of TSCA to Other EPA Authorities

EPA previously proposed a finding under §9(b) of TSCA that it was in the public interest to use TSCA instead of the Clean Air Act or the Federal Insecticide, Fungicide, and Rodenticide Act to regulate aerosol propellant uses of chlorofluorocarbons (42 FR 24545). EPA believes that that discussion of the disadvantages of using those acts remains applicable, and the Agency hereby adopts its proposed §9(b) findings.

The Clean Air Act Amendments of 1977 do not affect the Agency's authority to use TSCA to regulate the aerosol uses of chlorofluorocarbons. (42 U.S.C. 7458). The Amendments specifically permit EPA to promulgate rules proposed under TSCA prior to enactment of the Amendments, and the legislative history contemplates that EPA would do so.

VII. Phase II

The Administrator recognizes that this rule and the corresponding FDA regulation may not be adequate to fully protect the ozone layer. As EPA has indicated previously, nonpropellant uses such as refrigerants and solvents are being examined in the second phase investigation. A second public meeting on Phase II uses to gather pertinent information was held by EPA, FDA, and the Consumer Product Safety Commission (CPSC) in February.

In addition to EPA's general authority under TSCA to regulate chemical substances, the 1977 Amendments to the Clean Air Act specifically address the protection of the ozone layer (42 U.S.C. 7450). These provisions require EPA and other Federal agencies to conduct research and to submit reports to Congress on the stratosphere. By August 1979, EPA must submit a report to Congress that recommends further regulatory steps that may be needed. At that time the Administrator must propose regulations "for the control of any substance, practice, process, or activity (or any combination thereof) which in his judgment may be reasonably anticipated to affect the stratosphere, especially ozone in the stratosphere, if such effect in the stratosphere may reasonably be anticipated to endanger public health or welfare." (42 U.S.C. 7457).

EPA, CPSC, and FDA consequently will be engaged in an ongoing review of the ozone problem after this regulation has been promulgated and becomes effective. Should it become apparent in the future that chlorofluorocarbons do not pose an unreasonable risk, the Agency will take appropriate action to rescind or modify this rule.

VIII. Essential Uses

During the development of this rule, a number of persons requested exemptions for the use of certain products which contain chlorofluorocarbon propellants. Essential uses that were granted exemptions are listed in §762.21 of the rule. The criteria used, the products considered, and the information analyzed in evaluating all requests are found in the support document "Essential Use Determinations-Revised." All of the essential uses will be reevaluated during the second phase of EPA's regulation of chlorofluorocarbons.

The four most significant categories of essential uses considered by EPA were pesticides, products used by the Department of Defense (DOD), uses in the electronics/electrical industries, and uses in the aviation industry. For the reasons described in the essential

use document, only a few pesticide uses were granted exemptions. DOD uses are covered by a Memorandum of Understanding between EPA and DOD which is publicly available. Under its terms DOD will be able to use only those products necessary to maintain the military preparedness of the United States. DOD will switch to alternative products where they exist.

Electronic/electrical uses and aviation uses are broad categories of uses. These categories were given exemptions because most of the products within both of the categories are important for preserving public safety and promoting public welfare. At this time, the Agency does not have the information necessary for limiting these broad exemptions in order to identify nonessential products. However, the Agency will examine these products in depth during its Phase II examination of chlorofluorocarbons.

IX. Preemption of State Laws

This regulation affects the authority of a State to establish regulations concerning chlorofluorocarbons. Section 18 of TSCA provides that when EPA restricts the manufacture of or otherwise regulates a chemical under section 6, a State may only issue requirements which are identical, which are mandated by other Federal laws, or which prohibit the use of the chemical. Thus, this regulation preempts any less restrictive State regulation addressed to the same risk.

X. Legal Considerations

These rules are being promulgated under the authority of sections 6, 8, and 12 of TSCA (15 U.S.C. 2605, 2607, 2611).

A. Relationship of Rule to Federal Food, Drug, and Cosmetic Act

Section 762.11, as proposed, prohibited any person from manufacturing chlorofluorocarbons for any aerosol propellant use after October 15, 1978, except for those uses found to be essential by EPA and FDA. Several commenters challenged EPA's legal authority to do this under TSCA section 3(2)(B)(vi). They specifically argued that TSCA does not empower EPA to regulate all the manufacture of a chemical that has many uses if that chemical sometimes functions as a food, drug, or cosmetic.

EPA concurs in large part with these comments and has amended the regulation accordingly. Section 762.11(a)(1) no longer prohibits manufacture under TSCA for food, food additive, drug, cosmetic, or device uses (hereinafter referred to as "FFDCA substances"). However, a rule promulgated by the FDA today prohibits most uses of chlorofluorocarbons in FFDCA substances.

EPA agrees that TSCA does not provide the authority to regulate FFDCA substances insofar as a chemical is actually manufactured, processed, or distributed in commerce for use as an FFDCA substance. The Agency also recognizes that the definition of "drug" includes a chemical intended for use as a component of a drug and that components of foods, food additives, cosmetics, and devices are similarly treated in the FFDCA. Chlorofluorocarbons can, however, be used either as components of FFDCA substances or for other purposes. Because all chlorofluorocarbon propellants are manufactured in the same way, physical examination of a chlorofluorocarbon does not reveal its intended use. The manufacturer's intent determines the prospective use.

In order to be exempt from this section 6 rule, the manufacturer would have the burden of demonstrating his intent to manufacture the propellant for use as an FFDCA substance. EPA has concluded that where a chemical such as a chlorofluorocarbon is being manufactured both for use as an FFDCA substance and for other uses, the chemical will be presumed to be a chemical substance under TSCA unless it clearly can be shown that the chemical actually is being manufactured for use as an FFDCA substance. This presumption is particularly appropriate here since it is anticipated that the vast majority of chlorofluorocarbons manufactured after October 15, 1978, will be produced for uses other than uses as FFDCA substances, i.e., for propellant uses found to be essential under EPA's regulation or for nonpropellant uses such as refrigerants and solvents.

As a practical matter, EPA and FDA believe that the legal determination of whether a chlorofluorocarbon is a TSCA chemical substance or an FFDCA substance will be of minimal significance except with respect to separate enforcement of EPA's and FDA's regulations. Both rules have the same general purpose, namely, to ban most uses of chlorofluorocarbons as aerosol propellants. There is no regulatory gap. If a chlorofluorocarbon is not a TSCA chemical substance, it is an FFDCA substance, and vice versa.

B. Relationship of Rule to Federal Insecticide, Fungicide, and Rodenticide Act

Proposed § 762.12 did not prohibit processing of chlorofluorocarbon propellants for use in pesticide products. EPA requested comments on whether TSCA section 3(2)(B)(ii) permits EPA to regulate under TSCA the processing of chlorofluorocarbons which may take place as part of the manufacture of pesticide products (42 FR 24545). No comments on this point were received. Having considered the issue further, both in connection with this regulation and the TSCA section 8(a) inventory reporting regulation, EPA has concluded that there is sufficient authority under TSCA to ban the processing of chlorofluorocarbons for use in pesticides (i.e., incorporation of chlorofluorocarbons into aerosol pesticides).

In order to be considered a pesticide, a chemical substance must be intended for use as a pesticide.[1] Raw materials, intermediates, and inert ingredients such as chlorofluorocarbons used in the manufacture of a pesticide are not regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) unless they happen to be pesticides themselves. A chlorofluorocarbon would fall within the jurisdiction of FIFRA only when it has become a component of a pesticide product. This would not occur until it was actually mixed with or combined with the active ingredient (the pesticide).

The legislative history of TSCA indicates that a particular chemical could be subject to both TSCA and FIFRA at different points in time. When the bill which became TSCA was under Senate floor consideration, Senator Allen specifically addressed the interface between FIFRA and TSCA noting that the bill's provision meant that: "* * * any chemical or toxic substance would first be subject to the provisions of TSCA and yet when it becomes a component of a pesticide, it would be subject to FIFRA. In many instances, the manufacturer of the component is also the manufacturer and registrant of the pesticide." Committee on Interstate and Foreign Commerce, 94th Cong., 24 Sess. Legislative History of the Toxic Substances Control Act 232 (1976).

The change in § 762.12 does not significantly alter the practical impact of this regulation because a ban on manufacturing for pesticide uses was previously proposed (§ 762.11). It will, however, greatly aid the Agency in its enforcement efforts since the enforcement emphasis will be on processors.

C. Exports

Several commenters argued that the proposed ban on export is beyond EPA's authority under TSCA. It was stated that the export of food, drugs, and cosmetics is being regulated contrary to the intent of section 3(2) of TSCA and section 801(d) of the FFDCA. The Administrator disagrees in part with the above analysis; however, changes in the rule make it unnecessary to resolve those issues.

The only regulation of exports in the final rule appears in the processing ban provision (§ 762.12(b)). Pro-

[1] This issue is also discussed in the response to comments 37 and 39 on the section 8(a) inventory rule. (42 FR 64586-7, Dec. 23, 1977.)

cessing of chlorofluorocarbons into aerosol propellant articles intended for export is prohibited after December 15, 1978. Exemptions permitting processing for essential uses and for use in FFDCA substances apply equally to both articles intended for domestic use and articles intended for export. The final rule does not prohibit either the manufacture for export or the export of articles containing chlorofluorocarbon aerosol propellants. The Agency believes that regulation of the processing of chlorofluorocarbon propellants into export articles is adequate to reduce the risk associated with export of chlorofluorcarbon aerosol propellants.

EPA decided not to regulate the manufacture and export distribution of the unprocessed chlorofluorocarbon until Phase II or until such time as EPA discovers that increasing quantities of chlorofluorocarbons are being exported for processing abroad into propellant articles. A major factor in this decision was that the export of the unprocessed substance for propellant uses appears to be minimal, especially in contrast to the export for uses such as refrigerants, which are not subject to the Phase I regulation. EPA may also decide to use its authority under the ozone protection section of the Clean Air Act (42 U.S.C. 7450) to address the export issue. Lastly, a limited ban on the export of the bulk chemical (i.e., only for nonessential propellant uses) would be difficult to enforce.

The revisions in the rule have been made by deleting the references to "export" in the definitions of manufacture, processing, and distribution in commerce, and by adding a new § 762.12(b) which prohibits processing for export.

In addition to the concern about the scope of the export ban, commenters questioned EPA's proposed finding that the export of chlorofluorocarbon propellant articles presents an unreasonable risk of injury to health and the environment of the United States. Commenters stated that the finding was inadequate and that further quantification of the risk is necessary.

EPA disagrees with the comment. While further quantification of all risks associated with chlorofluorocarbons is desirable, it is clear that all discharges contribute to the depletion of the ozone layer, that increased emissions pose correspondingly greater risks, and that discharges anywhere in the world affect health and the environment of the United States. Thus, the Administrator believes that the export of chlorofluorocarbon aerosol propellants presents the same unreasonable risk of injury as domestic use and that steps should be taken to reduce that risk, both to protect the United States' population and environment and to emphasize the United States' concern over domestic and worldwide discharges.

Persons planning to export chlorofluorocarbons should be aware that section 12(b) of TSCA requires exporters to notify the Administrator of any exportation. Procedures for complying with this reporting requirement will be published shortly.

D. REPORTING REQUIREMENTS

The reporting rule is being issued under the authority of TSCA sections 6 and 8. It is intended to monitor compliance with the rule. On the basis of information received in the reports, EPA's Office of Enforcement will be able to direct inspections to those facilities which are most likely to be in violation of the cholorofluorocarbon ban rule. Consequently, facilities which are in compliance with the ban rule will not be required to undergo needless inspection, and EPA resources will not be devoted to unnecessary inspection tasks. In addition, top level management of facilities which manufacture or process chlorofluoroalkanes will be made continually aware of the substance and scope of the chlorofluorocarbon ban rule via the requirement that they personally sign the reports.

In connection with § 712.3, one manufacturer questioned EPA's legal authority to require businesses to submit customer lists. The manufacturer stressed that while TSCA section 8(a) specifies a number of types of information which the Administrator may require to be reported, it makes no mention of customer lists. This argument is not convincing. The legislative history clearly contemplates that the Administrator is to be given access to information necessary for effective enforcement of the Act, and further emphasizes that the types of information described in section 8(a) are only illustrative.

Manufacturers, of course, may make confidentiality claims for their customer lists in accordance with EPA procedures on disclosure of confidential business information. 40 CFR Part 2.

XI. Discussion of the Rule

Some of the reasons for changes from the proposal are discussed in the previous section on Legal Considerations. That discussion should be referred to for a fuller understanding of the revisions.

A. SCOPE

In response to a comment that § 762.1 could be construed ambiguously, the wording has been revised to reflect clearly the intended meaning.

In order for a substance to be subject to this rule, it must be (a) a fully halogenated chlorofluoroalkane, (b) used as an "aerosol propellant," and (c) a "chemical substance" as defined in section 3(2) of TSCA. A fully halogenated chlorofluoroalkane is any molecule which has only chlorine, fluorine, and carbon atoms and which does not have a double or triple bond between two carbon atoms.

B. DEFINITIONS

"Aerosol propellant" means a gas which is used to expel different material from a container. Therefore, if a chlorofluorocarbon is used as an active ingredient, it is not an "aerosol propellant" within the meaning of this rule. If, for example, chlorofluorocarbon F-12 is used to expel chlorofluorocarbon F-113 from the container, only the propellant F-12 would be subject to this regulation. Similarly, if the entire contents in this container consist of one type of chlorofluorocarbon, such as F-12 in a chiller, the product is not subject to Phase I regulation. The nonpropellant aerosol uses will be addressed in the Phase II investigation.

The definitions for "Administrator," "chemical substance," "commerce," "processor," "State," and "United States" have been deleted from the rule. These words have the exact definitions given to them in TSCA (15 U.S.C. 2602), and there is no need to repeat the definitions in the rule.

The definitions for "manufacture," "processing," "distribute in commerce," and "distribution in commerce" also have been omitted. The deletions of the special provisions relating to exports which were included in the proposed rule now make these definitions identical to the ones appearing in TSCA. (A discussion of the regulation of exports is found above under Legal Considerations.)

Definitions for "person" and "nonconsumer article" have been added. The definition for "bulk distributor" has been deleted because the term is not used in the final rule.

C. BANS AND EXEMPTIONS

In general, manufacture of chlorofluorocarbons for aerosol propellant uses is prohibited after October 15, 1978. Processing and distribution of unprocessed chlorofluorocarbons are prohibited after December 15, 1978. Exemptions from these general prohibitions are discussed below.

The manufacturing ban (§ 762.11) contains three exemptions. First, manufacture for use in FFDCA substances is not prohibited by this rule. Second, essential uses are exempt. Third, unprocessed chlorofluorocarbons and articles containing chlorofluorocarbon propellants may be imported before December 16, 1978. As discussed at proposal (42 FR 24546), this third exemption alleviates an economic disparity that would otherwise occur in the

treatment of foreign and domestically produced chlorofluorocarbons.

The wording of the third exemption has been changed since proposal to clarify the Agency's intent that the import of chlorofluorocarbons in any form for aerosol propellant uses is prohibited. If EPA exempted the importation of chlorofluorocarbon propellant substances and articles, the effect of this rule could be rendered meaningless by the mass production abroad and importation into the United States of aerosol products for which the manufacture and processing are banned here.

A new § 762.11(c) requires manufacturers of chlorofluorocarbons for aerosol propellant uses to obtain signed statements from their customers that the chlorofluorocarbons are being purchased for aerosol propellant uses permitted by EPA or FDA, or for other uses. These statements will enable the manufacturers to assure themselves that they are manufacturing chlorofluorocarbons in compliance with this rule.

As long as a manufacturer makes chlorofluorocarbons for any propellant use, he must obtain a statement from all his customers (although he need not report nonpropellant customers to EPA under 40 CFR 712.3). While manufacturers who do not make any chlorofluorocarbons for aerosol propellant uses are not required to report to EPA, they are still subject to § 762.11(a). Hence, such manufacturers still have the burden of being able to demonstrate that they are manufacturing chlorofluorocarbons legally.

The processing ban (§ 762.12), as, in the proposal, prohibits processing chlorofluorocarbon propellants for domestic or foreign distribution, but it exempts FFDCA substances and essential uses. The final rule also has been changed to prohibit the processing of chlorofluorocarbons for use in pesticide products (as discussed in the Legal Consideration section).

The distribution ban (§ 762.13(a)) prohibits any person from distributing chlorofluorocarbons for processing into aerosol propellant articles after December 15, 1978. Use in FFDCA substances and essential uses are exempted from this section.

The final rule does not regulate the distribution in commerce of articles containing chlorofluorocarbon aerosol propellants (proposed § 762.13(b)). EPA believes that regulation of manufacturing, processing, and distribution in commerce of the unprocessed chemical will be sufficent to eliminate the unreasonable risk to health and the environment.

D. REPORTING

The reporting requirements have been revised in order to reduce and clarify them. They will cover fewer than 100 businesses, and the annual cost of compliance to most of these businesses will range from $20 for one processor to $5,000 for the one of the larger manufacturers.

Annual reports must be submitted by all persons who manufacture and/or process chlorofluorocarbons for aerosol propellant uses subject to TSCA. (Importers are included within the definition of manufacturer by virtue of section 3(7) of TSCA.) If a manufacturer or processor closes his business in 1979, 1980, or 1981, he must submit an annual report for his last calendar year of operations.

Manufacturers reports must list customers who purchase chloroflurocarbons for aerosol propellant uses, the quantity sold to each of those customers, and the total quantity manufactured for all uses. If none of a manufacturer's customers purchase chlorofluorocarbons for aerosol propellant uses, the manufacturer is not required to submit an annual report to EPA. If a customer purchases chlorofluorocarbons for propellant and nonpropellant uses, the quantities purchased for each category must be indicated. Manufacturers will be able to determine the purpose for which the chlorofluorocarbons are being purchased by examining the signed statements obtained in accordance with § 762.11(c). A manufacturer must submit one annual report covering manufacture in all of his facilities, and the report must conform to the format indicated in the rule.

Processors reports must list the manufacturers or distributors from whom they purchased chlorofluorocarbons, the quantity purchased from each seller, and the quantity processed for each aerosol propellant use. The final rule has been revised so that processors are not required to report the names of their customers. A processor must submit a separate report for each one of his processing facilities, and each report must conform to the format indicated in the rule.

Processors who do not process for aerosol propellant uses are not required to report. If all of the aerosol propellant articles processed by a processor are regulated solely by FDA, the processor does not have to comply with these reporting requirements. If a processor processes both for aerosol propellant uses regulated by FDA and for aerosol propellant uses regulated by EPA, he must report to EPA. Reports submitted to EPA need not specify particular food, drug, and cosmetic uses.

The final rule requires that annual reports be submitted in March of 1980, 1981, and 1982. The 1980 manufacturers report must cover manufacturing from October 16, 1978, through December 31, 1979. The 1980 processors report must cover processing from December 16, 1978, through December 31, 1979. Subsequent annual reports must provide information for the preceding calendar year. Reports must be submitted by registered mail to EPA's headquarters in Washington, D.C. In order to facilitate reading the reports, new provisions require that the reports be written according to a specified format.

ECONOMIC IMPACT ANALYSIS STATEMENT

The economic support document "The Economic Impact of Potential Regulation of Fluorocarbon Aerosols" comprises the economic impact analysis statement required by Executive Order 11821 and OMB Circular A-107.

Dated: March 10, 1978.

DOUGLAS M. COSTLE,
Administrator.

A part 762 is established to read as follows:

OFFICIAL RECORD OF RULEMAKING—FULLY HALOGENATED CHLOROFLUOROALKANES

Section 19(a)(3) of TSCA defines the term "rulemaking record" for purposes of judicial review as follows:

For purposes of this section, the term "rulemaking record" means—

(A) The rule being reviewed under this section;

(B) In the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a), the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be;

(C) Any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;

(D) Any written submission of interested parties respecting the promulgation of such rule; and

(E) Any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the FEDERAL REGISTER.

In accordance with the requirements of section 19(a)(3)(E) quoted above, EPA is publishing the following list of documents constituting the record of this rulemaking. Public comments and submissions made at the rulemaking hearing and in connection with it are exempt from the FEDERAL REGISTER listing under section 19(a)(3) and therefore have not been listed. However, a full listing of these materials is available on request from the Record and Hearing Clerk.

DOCUMENTS

PROPOSED REGULATION

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Sec.
762.1 Scope.
762.2 Definitions.
762.11 Manufacture: Prohibitions, Exemptions, and Certification Requirements.
762.12 Processing: Prohibitions and Exemptions.
762.13 Distribution in Commerce: Prohibitions and Exemptions.
762.21 Essential Use Exemptions.

AUTHORITY: Toxic Substances Control Act, 15 U.S.C. 2605, 2611.

§ 762.1 Scope.

This part prohibits the manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes for those aerosol propellant uses which are subject to the Toxic Substances Control Act (TSCA) and lists the exemptions to the prohibitions.

§ 762.2 Definitions.

For the purposes of this Part:

(a) The term "aerosol propellant" means a liquefied or compressed gas in a container where the purpose of the liquefied or compressed gas is to expel from the container liquid or solid material different from the aerosol propellant.

(b) The term "person" includes any natural person, corporation, firm, company, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

(c) The term "nonconsumer article" means any article subject to TSCA which is not a "consumer product" within the meaning of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2052.

(d) The terms "Administrator," "chemical substance," "commerce," "distribute in commerce," "manufacture," "process," "processor," "State," and "United States" have the same meanings as in 15 U.S.C. 2602.

§ 762.11 Manufacture: prohibitions, exemptions, and certification requirements.

(a) After October 15, 1978, no person may manufacture, except to import, any fully halogenated chlorofluoroalkane for any aerosol propellant use except as follows:

(1) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602;[1] or

(2) For those essential uses listed in § 762.21.

(b) After December 15, 1978, no person may import into the customs territory of the United States any fully halogenated chlorofluoroalkane, whether as a chemical substance or as a component of a mixture or article, for any aerosol propellant use except as follows:

(1) For use in an article which is a food, food additive, drug cosmetic, or device exempted under U.S.C. 15 2602; or

(2) For those essential uses listed in § 762.21.

(c) Every person manufacturing fully halogenated chlorofluoroalkanes for aerosol propellant uses after October 15, 1978, must obtain a signed statement from every person purchasing the fully halogenated chlorofluoroalkanes from him for any use. This statement must specify whether the fully halogenated chlorofluoroalkanes are being purchased (1) for aerosol propellant uses permitted under either 40 CFR Part 762 or 21 CFR 2.125 or (2) for other uses.

§ 762.12 Processing: prohibitions and exemptions.

(a) After December 15, 1978, no person may process any fully halogenated chlorofluoroalkane into any aerosol propellant article except as follows:

(1) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(2) For those essential uses listed in § 762.21.

(b) After December 15, 1978, no person may process any fully halogenated chlorofluoroalkane into any aerosol propellant article intended for export except as follows:

(1) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(2) For those essential uses listed in § 762.21.

§ 762.13 Distribution in commerce: prohibitions and exemptions.

After December 15, 1978, no person may distribute in commerce any fully halogenated chlorofluoroalkane for processing into any aerosol propellant article except as follows:

(a) For use in an article which is a food, food additive, drug, cosmetic, or device exempted under 15 U.S.C. 2602; or

(b) For those essential uses listed in § 762.21.

§ 762.21 Essential use exemptions.

The following aerosol propellant uses of fully halogenated chlorofluoroalkanes are essential and exempt from §§ 762.11–762.13:

(a) Mercaptan stench warning devices.

(b) Release agent for molds used in the production of plastic and elastomeric materials.

(c) Flying insect pesticides for use in nonresidential food handling areas except when applied by total release or metered valve aerosol devices, and for space spraying of aircraft.

(d) Diamond-grit spray.

(e) Nonconsumer articles used as cleaner-solvents, lubricants, or coatings for electrical or electronic equipment.

(f) Articles necessary for safe maintenance and operation of aircraft.

(g) Uses essential to the military preparedness of the United States as determined by the Administrator and the Secretary of Defense.

Sec.
712.1 Scope.
712.2 Definitions.
712.3 Reporting requirements for manufacturers of fully halogenated chlorofluoroalkanes for aerosol propellant uses.
712.4 Reporting requirements for processors of fully halogenated chlorofluoroalkanes for aerosol propellant uses.
712.5 General reporting requirements.

AUTHORITY: Toxic Substances Control Act, 15 U.S.C. 2605, 2607.

§ 712.1 Scope.

This Part requires manufacturers and processors of fully halogenated chlorofluoroalkanes for aerosol propellant uses to submit annual reports to the Environmental Protection Agency. It is intended to facilitate the enforcement of Part 762 of this chapter.

[1] The Food and Drug Administration has promulgated separate regulations on use of fully halogenated chlorofluoroalkanes in these articles at 21 CFR 2.125.

§ 712.2 Definitions.

The terms used in this Part shall have the same meanings as in Part 762.2 of this chapter.

§ 712.3 Reporting requirements for manufacturers of fully halogenated chlorofluoroalkanes for aerosol propellant uses.

(a) Every person who after October 15, 1978, manufactures fully halogenated chlorofluoroalkanes for aerosol propellant uses subject to the Toxic Substances Control Act (TSCA) must submit an annual report.

(b) Every annual report submitted by a manufacturer must contain the following information and conform to the following format:

(1) Page one:

(i) Name of business,

(ii) Business address,

(iii) Chief executive officer,

(iv) Addresses of all facilities at which fully halogenated chlorofluoroalkanes are manufactured,

(v) Name, business address, and telephone number of individual most knowledgeable of the contents of this report.

This report covers manufacture of fully halogenated chlorofluoroalkanes for aerosol propellant uses from (date to date).

(2) Page two (and subsequent pages is necessary):

Purchaser	Shipping addresses	Total quantity purchased (in pounds)	Quantity for aerosol propellant uses (in pounds)	Quantity for other uses (in pounds)
List name of customers who purchased for aerosol propellant uses.	(List)	(List)	(List)	(List)

State total quantity in pounds of fully halogenated chlorofluoroalkanes manufactured for all uses for the time period covered by this report.

(3) At the bottom of the last page make the following statement and certification:

I understand that I may assert a claim of business confidentiality by marking any part or all of this information as "TSCA Confidential Business Information" and that information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR Part 2. I further understand that if I do not mark this information as confidential, EPA may disclose it publicly without providing me notice of an opportunity to object.

I certify that to the best of my knowledge the contents of this report are accurate and complete.

Date _____
Signed _____
Position Title _____

(4) The statement and certification required by paragraph 3 of this section must be signed by the chief executive officer of the manufacturer.

§ 712.4 Reporting requirements for processors of fully halogenated chlorofluoroalkanes for aerosol propellant uses.

(a) Every person who after December 15, 1978, processes fully halogenated chlorofluoroalkanes for aerosol propellant uses subject to the Toxic Substances Control Act must submit an annual report. A separate report must be submitted for each processing facility.

(b) Every report submitted by a processor must contain the following information and conform to the following format:

(1) Page one:

(i) Name of business,

(ii) Business address,

(iii) Chief executive officer,

(iv) Facility address,

(v) Name, business address, and telephone number of individual most knowledgeable of the contents of this report.

This report covers purchases and processing of fully halogenated chlorofluoroalkanes for aerosol propellant uses from (date to date).

(2) Page 2 (and subsequent pages if necessary):

Purchases of fully halogenated chlorofluoroalkanes:

Purchased from and quantity purchased (in pounds)

(list names and business addresses) (list).

Processing of fully halogenated chlorofluoroalkanes:

Use and Quantity (in pounds)

1. Mercaptan mine warning device (list).
2. Release agent.
3. Pesticides.
4. Diamond-grit spray.
5. Electrical/electronic.
6. Aviation.
7. Defense.
8. Food, food additives, drugs, cosmetics, and devices.
9. Other (explain).

(3) At the bottom of the last page make the following statement and certification:

I understand that I may assert a claim of business confidentiality by marking any part or all of this information as "TSCA Confidential Business Information" and that information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR Part 2. I further understand that if I do not mark this information as confidential, EPA may disclose it publicly without providing me notice of an opportunity to object.

I certify that to the best of my knowledge the contents of this report are accurate and complete.

Date _____
Signed _____
Position Title _____

(4) The statement and certification required by paragraph 3 of this section must be signed by the highest offical at the processing facility for which the report is being submitted.

§ 712.5 General reporting requirements.

(a) Annual reports must be submitted by March 31, 1980, 1981, and 1982. The 1980 manufacturers report must cover maufacturing from October 16, 1978 through December 31, 1979. The 1980 processors report must cover processing from December 16, 1978, through December 31, 1979. Subsequent annual reports must provide information for the preceding calendar year.

(b) Annual reports must be submitted to the Pesticides and Toxic Substances Enforcement Division, Office of Enforcement (EN-342), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

(c) Annual reports must be submitted by registered mail.

[FR Doc. 78-7120 Filed 3-16-78; 8:45 am]

[6355-01]

CONSUMER PRODUCT SAFETY COMMISSION

FULLY HALOGENATED CHLOROFLUOROALKANES AS PROPELLANTS IN AEROSOL CONSUMER PRODUCTS

Commission Action in Response to the Environmental Protection Agency's Ban

In this document, the Consumer Product Safety Commission (CPSC) announces that, in view of the Environmental Protection Agency's (EPA) final rules appearing elsewhere in this issue of the FEDERAL REGISTER prohibiting almost all of the manufacture, processing, and distribution in commerce of fully halogenated chlorofluoroalkanes (chlorofluorocarbons) for those aerosol propellant uses which are subject to the Toxic Substances Control Act (TSCA), banning action by the CPSC is unnecessary.

Previously, the Commission had preliminarily concluded that aerosol consumer products which use certain chlorofluorocarbon propellants should be banned because they present an unreasonable risk of injury to consumers from the destruction of the stratospheric ozone layer and no feasible consumer product safety standard would adequately protect the public. The Commission's staff was directed to work with EPA and the Food and Drug Administration (FDA), which had announced their intentions to phase out the non-essential uses of fluorocarbons in products under their jurisdiction. Subsequently, the Commission reviewed the ban that was proposed by EPA and determined that banning action by the Commission was unnecessary at that time (42 FR 24550, May 13, 1977).

Except for those products that have been deemed by EPA to be "essential," the final EPA ban applies to all products using these chlorofluorocarbons as propellants to expel other materials from a container that are subject to the jurisdiction of the Commission. After considering the terms of the final ban issued by EPA, the Commission still believes that it is not necessary for it to take any banning action in addition to that already taken by EPA.

The Commission did, however, issue a final rule (16 CFR Part 1401, 42 FR 42780, August 24, 1977), effective February 20, 1978, that requires labeling of consumer products containing these chorofluorocarbon propellants and requires the manufacturers of such products to submit product identifying information to the Commission. This labeling rule is somewhat broader than the EPA ban in that it applies to "essential" as well as nonessential products and to products in which the propellant is the only substance expelled.

The Commission's staff is continuing to cooperate closely with the EPA and the FDA through the Interagency Chlorofluorocarbon Work Group (a committee including EPA, FDA and CPSC representatives) as it explores the possible regulation of certain chlorofluorocarbons in non-aerosol uses.

Dated: February 23, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

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